

# Exhibit 1

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*Attorneys for Defendants*  
*C. R. Bard, Inc. and*  
*Bard Peripheral Vascular, Inc.*

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF ARIZONA

IN RE: Bard IVC Filters Products Liability  
Litigation

No. 2:15-MD-02641-DGC

**DECLARATION OF ROBERT  
CARR IN SUPPORT OF  
DEFENDANTS' MOTION TO  
ENFORCE PROTECTIVE ORDER  
OVER CERTAIN TRIAL EXHIBITS**

(Assigned to the Honorable David G.  
Campbell)

I, Robert Carr, declare under penalty of perjury, pursuant to 28 U.S.C. § 1746, that the following is true and correct to the best of my knowledge and belief:

1. I am over 18 years of age and am competent to testify about the matters contained herein. The statements contained herein are based on my personal knowledge and upon the basis of the documents maintained by Defendants C. R. Bard, Inc. and Bard

1 Peripheral Vascular, Inc. (collectively, "Bard") in the regular course of business.

2 2. I am presently employed as the Vice President of International at Bard  
3 Peripheral Vascular, Inc. ("BPV") a subsidiary of C. R. Bard, Inc. ("C. R. Bard"). Until  
4 October 2015, I was Senior Director of Research and Development at BPV. Bard  
5 manufactures and distributes inferior vena cava ("IVC") filters and has manufactured and  
6 distributed the Recovery® Filter, G2® Filter, G2® Express Filter, G2®X Filter, Eclipse®  
7 Filter, Meridian® Filter, and Denali® Filter (collectively, "Bard IVC Filters"), each of  
8 which is a medical device cleared by the Food and Drug Administration ("FDA")  
9 indicated for treatment of blood flow problems posing the risk of pulmonary embolism.  
10 Before joining BPV in 2002, I was employed by Nitinol Medical Technologies ("NMT"),  
11 where I was also responsible for that company's research and development of IVC filters.

12 3. This declaration is based upon my personal knowledge and review of certain  
13 business records prepared and maintained in the ordinary course of business of Bard that  
14 were, to a limited extent, used during the trials in this MDL. This declaration is also based  
15 upon my personal knowledge of how the trial exhibits were used during my testimony  
16 during trial. Many of the documents at issue relate to Bard Filters other than the  
17 generations implanted in the plaintiffs, and/or include information related to Bard's  
18 medical devices other than IVC filters. I could and would competently testify to the  
19 matters set forth herein if called as a witness in this matter.

20 4. Attached as Exhibit "A" is a chart further discussing the documents  
21 identified in parentheses below by trial exhibit number.

22 5. As part of and during the course of my work with Bard and NMT, I have  
23 become familiar with documentation and records associated with the design, development,  
24 manufacture, regulatory compliance, and testing (including clinical testing) of the Bard  
25 IVC Filters. The documentation and records include:

- 26 a. Design assessment documents, including analysis of adverse events to  
27 inform design modifications (0354) and Design Failure Mode and Effects  
28 Analyses (0631, 0635, 1763, 4457);

- b. Volume 2 of the Meridian Design History File, which alone is over 1,500 pages, and only one page of which was admitted during trial (1861);
- c. Design input and performance documents, including Design Input Summaries (4455), Product Performance Specifications (4420, 4456, 4897), Project Plans (4486), and product development documents (6089, 8572, 8573, 8583);
- d. Animal and bench testing (4896, 5384, 5385, 5929, 5934, 8358, 8359, 8368, 8373, 8546, 8574, 8575); and,
- e. Documents related to regulatory requirements such as FDA filings and correspondence that include, incorporate, or otherwise discuss some or all of the above types of design and testing documents (0691, 4603, 5272, 5273, 5379, 5486, 5488, 5586, 5587, 5588, 5593, 5512, 6013).

6. As part of and during the course of my work with NMT and Bard, I have become familiar with documentation and records associated with quality system procedures, complaint and adverse event responses, reporting, and handling, device tracking procedures, and corrective action procedures with regard to Bard Filters. The documentation and records include:

- a. Internal adverse event analyses, including complaint tracking and trending, Failure Investigation Memoranda, and Health Hazard Evaluations (0443, 0447, 0614, 0677, 0769, 0924, 1140, 4469, 4607, 4820, 4895, 5970);
- b. Monthly management reports providing senior management with adverse event analyses (4504, 4507, 4509, 4512, 4514, 4515, 4519, 4522, 4528, 4532, 4533, 4534);
- c. A chart of various adverse event analyses compiled for this litigation (4565);
- d. Risk analyses for different IVC filter generations, including risks of the manufacturing process and inherent characteristics of the product (4895, 5967);

- e. Quality Management Board Review presentation, which includes Quality Assurance analysis, such as adverse event tracking and trending, corrective action and audit information, and other extensive Quality Assurance information for all of BPV's products (5946); and,
- f. Standard and Division Operating Procedures and corporate policies for risk analysis and management (5563, 5565, 7961, 7962).

7. As part of and during the course of my work with NMT and Bard, I have become familiar with documentation and records associated with the sales and market analysis of the Bard Filters. The documentation and records include:

- a. Concept and Idea Product Opportunity Appraisals analyzing the IVC filter market, various design issues, and financial data (0504, 0591, 0770, 1742, 4454);
- b. Filter Franchise Reviews analyzing Bard's and competitors' lines of IVC filters, including design issues and financial data (0571); and,
- c. Commercialization Plans, Post-Market Reviews, and other sales and competitor analysis including market strategies and financial analysis (1568, 1788, 2238, 4468, 7900).

8. As part of and during the course of my work with Bard, I have become familiar with Bard's record-keeping procedures. I have personal knowledge of the roles and responsibilities of Bard's employees responsible for this record-keeping process. The business documents referenced herein were prepared and maintained in the ordinary course of Bard's business, and it was the regular practice of Bard to make such records. These documents were prepared at or near the time of the events they record by persons with knowledge of the recorded events or from information transmitted by persons with knowledge of the recorded events.

9. Bard or its affiliates are engaged in the development, design, manufacturing, and distribution of medical devices, including the Bard Filters. Many documents

1 involving the Bard IVC Filters are confidential and are maintained as such by Bard for the  
2 reasons listed below.

3 10. The medical device business for IVC filters is a highly technical and  
4 sophisticated industry. It is also a highly competitive industry in which each company  
5 carefully guards its company documents, data, systems, processes, research and  
6 development, analysis, marketing strategies and trade secrets from competitors.

7 11. As part of and during the course of my work with Bard, I have become  
8 familiar with Bard's efforts to protect its trade secret and confidential proprietary  
9 information and documents. This information is maintained internally at Bard and  
10 distributed to employees who need to know the information to perform their duties. It is  
11 not available outside the company. Outside physician consultants working with the  
12 company who have access to this information sign confidentiality agreements.  
13 Additionally, Bard has always sought a Protective Order or Confidentiality Agreement  
14 during the course of civil lawsuits in order to protect their confidential, proprietary and  
15 trade secret information

16 12. The information contained in the documents referenced in Exhibit "A"  
17 required years for Bard to develop and is Bard's critical business information which is not  
18 made public by Bard.

19 13. The information contained in the documents referenced in Exhibit "A"  
20 would be of economic value to Bard's competitors. Moreover, such value would extend  
21 not only to manufacturers of other IVC filters, but also to manufacturers of other medical  
22 devices, as the value and utility of this information is not limited to IVC filters. The  
23 information contained in these documents could not only be used to benefit Bard's  
24 competitors, but also used actively against Bard to harm Bard's current and future  
25 interests.

26 14. Bard invests very substantial sums of money in medical device research,  
27 testing (including clinical testing), development, design, analysis, regulatory compliance,  
28 evaluation, and marketing. If the information Bard has developed over the years

1 pertaining to the Bard IVC Filters was obtained by its competitors, it would give an unfair  
2 economic advantage to those competitors.

3 I declare under penalty of perjury, under the laws of the United States, that the  
4 foregoing is true and correct.

5 Executed on this 26th day of October, 2018.

6   
7 Robert Carr

# EXHIBIT A



Exhibit	Admitted	Category	Carr Para.	DESCRIPTION	Jones Transcript	Hyde Transcript	BEGBATES	ENDBATES
0354	Hyde	Design	5(a)	9/19/2006 PPT re G2; Caudal Movement causes tilting which leads to perforation PPT last modified 3/16/2009 (custodian Mike Randall)		Admitted on transcript page 1497. Pages 1, 2, 5 and 9 displayed and discussed	BPVE-01-00665809	BPVE-01-00665809
0443	Hyde	Quality Assurance	6(a)	11/30/2008 G2 and G2X Fracture Analysis Reporting date range 7/1/2005 thru 11/30/2008		Admitted on transcript page 287. Pages 1, 2, 4, 6, 17, and 18 were displayed and discussed.	BPV-17-01-00170803	BPV-17-01-00170821
0447	Jones	Quality Assurance	6(a)	4/1/2009 Filter - Fracture Analysis (June 2010)	Admitted on transcript page 967, but not discussed or displayed		BPV-17-01-00170362	BPV-17-01-00170369
0504	Jones, Hyde	Market	7(a)	Eclipse Concept POA	Admitted on transcript page 2168, page 1 displayed at page 2169.	Admitted on transcript page 1398. First page displayed and discussed.	BPV-15-01-00108349	BPV-15-01-00108353
0571	Jones, Hyde	Market	7(b)	Baird Deposition 06/09/2016, Exhibit 301 - PowerPoint Presentation entitled BPV Filter Franchise Review dated 5/6/2008 (colored and 43 pages)	Admitted on transcript page 812. First page displayed on Page 822, Page 2 and 7 on transcript page 823	Admitted on transcript page 1100. Pages 2 and 7 displayed and discussed.		
0591	Jones, Hyde	Market	7(a)	Baird Deposition 06/09/2016, Exhibit 322 - Bard Idea POA on the Denali Filter, Project No. 8108 Rev. 0.0, revised August 2009 by Bret Baird	Admitted on transcript page 591. Pages 1 and 2 discussed and displayed on transcript page 853. Page 1 also displayed on transcript page 870 and 916	Admitted on transcript page 1134. Pages 2 and 3 discussed and displayed	BPVE-01-00546971	BPVE-01-00546975
0614	Jones, Hyde	Quality Assurance	6(a)	Betensky 02/2017 Expert Report - Adverse event reports and monthly sales totals through May 2011	Admitted on transcript page 1082, but not discussed or displayed.	Admitted on transcript page 754. First page published and discussed.	BPVEFILTER-01-00037664	BPVEFILTER-01-00037664
0631	Hyde	Design	5(a)	Betensky Expert Report - DFMEA070044, Rev. 3: G2 Express - Design Failure Mode and Effects Analysis		Admitted on transcript page 682. Pages 16, 20 and 26 displayed and discussed.	BPV-17-01-00139367	BPV-17-01-00139408
0635	Hyde	Design	5(a)	Betensky Expert Report - DFMEA070077, Rev. 1: Eclipse (Vail) Filter System - Design Failure Mode and Effects Analysis		Admitted on transcript page 684. Not displayed or discussed other than generally.	BPV-17-01-00191123	BPV-17-01-00191166
0677 - R	Jones	Quality Assurance	6(a)	Booker SOF Filter Fracture Analysis, August 2010, Reporting range 7/1/05 - 8/31/10, G2, G2X, and Eclipse	Admitted on transcript page 967 and 1297, but not displayed or discussed.		BPV-17-01-00170378	BPV-17-01-00170385
0691	Jones	Design	5(e)	Boyle, 02/02/2017, Exhibit 842 - E-mail chain first one from John Van Vleet to Steve Williamson, dated 11/5/2015, 6 pages	Admitted on transcript page 1890, but not discussed or displayed.		BPVEFILTER-37-00005826	BPVEFILTER-37-00005831
0769	Jones, Hyde	Quality Assurance	6(a)	Carr Deposition 12/19/2013, Exhibit 05 - BPV Meridian Claims Matrix, dated 7/2/2010	Admitted on transcript page 2173, page 1 displayed at page 2174.	Admitted on transcript page 1401, first page displayed and discussed.	BPV-17-02030532	BPV-17-02030534
0770	Jones, Hyde	Market	7(a)	Carr Deposition 12/19/2013, Exhibit 06 - Bard's Denali Concept Product Opportunity Appraisal, POA-8108, Rev. 1.0	Admitted on transcript page 705 and first page published, second page published on transcript page 707, and page 5 displayed on transcript page 744	Admitted on transcript page 1392. Pages 1 and 5 displayed and discussed.	BPV-DEP-00022350	BPV-DEP-00022358
0924 - R	Hyde	Quality Assurance	6(b)	Ciavarella Deposition 11/12/2013, Exhibit 26 - Chart of Sales and Adverse Events for all competitors from 01/00 through Q1 2006, according to the MAUDE database.		Admitted on transcript page 1371 before deposition of Dr. Ciavarella. Exhibit was not displayed or discussed in the as played deposition transcript.	BPVE-01-01631586	BPVE-01-01631679
1140 - R	Jones	Quality Assurance	6(a)	Ferrera Deposition 04/07/2017, Exhibit 25 - Presentation titled Filter-Fracture Analysis	Admitted on transcript page 1297, but not otherwise discussed.		BPVEFILTER-01-00303182	BPVEFILTER-01-00303190
1568	Jones, Hyde	Market	7(c)	Kessler Report - September 30, 2010 memo from Brett Baird to Eclipse DRT, with the subject line "Eclipse Post-Market Design Review/Marketing Summary,?" stated: "The objective of the Eclipse Filter project was to enhance the G2X filter surface finish?"	Admitted on transcript page 812, first page only displayed on page 847	Admitted on transcript page 1124. Pages 1 and 3 displayed and discussed	BPV-17-01-00170358	BPV-17-01-00170361
1742	Jones	Market	7(a)	Modra Deposition 06/06/2014, Exhibit 7 - Product Opportunity Appraisal for the G2 Platinum Concept, POA-8088 Rev. 1.0, Revised on 5/5/2009	Admitted on transcript page 885 and first page displayed.		BPVE-01-00597792	BPVE-01-00596801
1763	Hyde	Design	5(a)	Modra, 01/26/2017, Exhibit 771A - Chart entitled "Design Failure Mode and Effects Analysis" on the Simon Nitinol Filter - SNF/SL Filter Sets (DFMEA070042 Rev. 1)		Admitted on transcript page 680. Pages 1, 18 and 21 displayed and discussed.	BPVEFILTER-01-01725504	BPVEFILTER-01-01725526
1788	Jones, Hyde	Market	7(c)	Orms Deposition 08/16/2016, Exhibit 14 - 10/2/2010 E-mail Thread from Jeffrey Pellicio Re. "Meridian Commercialization Plan"	Admitted on transcript page 812, page 4 only published and discussed on page 868	Admitted on transcript page 1142. Pages 1, 4, 6 and 19 displayed and discussed.	BPVE-01-00580203	BPVE-01-00580233
1861	Hyde	Design	5(b)	Randall, 01/18/2017, Exhibit 634 - Binder labeled "Meridian Design History File DHF, Vol. II"		Page 70 of exhibit admitted on transcript page 301 and Page 38 of exhibit admitted on transcript page 303. No other pages admitted or discussed.	BPV-17-01-00149351	BPV-17-01-00151046
2238	Jones	Market	7(c)	Wilson, 01/31/2017, Exhibit 801 - E-mail string, Subject: Meridian Commercialization Plan	Admitted on transcript page 1082, but not otherwise discussed.		BPVEFILTER-01-00669757	BPVEFILTER-01-00669788
4420 - R	Jones, Hyde	Design	5(c)	Meridian Vena Cava Filter and Jugular Delivery System Product Performance Specification PPS, Revision 3	Admitted on transcript page 1082, but not otherwise discussed.	Admitted redacted on transcript page 1507. Pages 22 and 23 displayed and discussed.	BPV-17-01-00148748	BPV-17-01-00148749

4454	Jones, Hyde	Market	7(a)	Eclipse Vena Cava Filter Concept POA, Revision 2	Admitted on transcript page 812, pages 3 and 4 published and discussed on page 836	Admitted on transcript page 1111. Pages 3, 4 and 5 displayed and discussed.	BPV-17-01-00108346	BPV-17-01-00108353
4455	Jones, Hyde	Design	5(c)	Vail Vena Cava Filter DIS	Admitted on transcript page 812, page 1 displayed and discussed on page 837, page 3 displayed and discussed on page 838	Admitted on transcript page 1115. Page 3 displayed and discussed.	BPV-17-01-00108435	BPV-17-01-00108435
4456	Jones	Design	5(c)	Eclipse Vena Cava Filter Product Performance Specification (PPS)	Admitted on transcript page 812, but not otherwise discussed or displayed		BPV-17-01-00108440	BPV-17-01-00108508
4457	Jones	Design	5(a)	Vail Filter System DFMEA	Admitted on transcript page 812, but not otherwise discussed or displayed		BPV-17-01-00108531	BPV-17-01-00108578
4468	Jones	Market	7(c)	6/10/2011 email from Mike Randall re Meridian Presentation for SSM 2011	Admitted on transcript page 812, but not otherwise discussed or displayed		BPVEFILTER-09-00039353	BPVEFILTER-09-00039354
4469	Jones	Quality Assurance	6(a)	Data Source Evaluation memo from Natalie Wong to Quality Systems Coordinator, October 2010	Admitted on transcript page 812, wrong document displayed on page 855. Not otherwise discussed.		BPVEFILTER-29-00099320	BPVEFILTER-29-00099320
4486	Jones	Design	5(c)	G2 Express Project Plan FM0700150 Rev 6 1-30-07	Admitted on transcript page 1082, but not otherwise discussed.		BPV-17-01-00132328	BPV-17-01-00132337
4504 - R	Jones	Quality Assurance	6(b)	Monthly Management Report, dated 4/8/09	Admitted redacted on transcript page 1297, but not otherwise discussed.		BPVEFILTER-01-00340832	BPVEFILTER-01-00340851
4507 - R	Jones	Quality Assurance	6(b)	Monthly Management Report, dated 7/9/09	Admitted redacted on transcript page 1297, but not otherwise discussed.		BPVEFILTER-01-00229095	BPVEFILTER-01-00229114
4509 - R	Jones	Quality Assurance	6(b)	Monthly Management Report, dated 10/8/09	Admitted redacted on transcript page 1297, but not otherwise discussed.		BPVEFILTER-01-00193887	BPVEFILTER-01-00193907
4512 - R	Jones	Quality Assurance	6(b)	Monthly Management Report, dated 1/1/10	Admitted redacted on transcript page 1297, but not otherwise discussed.		BPVEFILTER-01-00191866	BPVEFILTER-01-00191886
4514 - R	Jones	Quality Assurance	6(b)	Monthly Management Report, dated 3/8/10	Admitted redacted on transcript page 1297, but not otherwise discussed.		BPVEFILTER-01-00195112	BPVEFILTER-01-00195131
4515 - R	Jones, Hyde	Quality Assurance	6(b)	Monthly Management Report, dated 4/8/10	Admitted at page 2160, discussed page 12 at page 553, page 13 discussed at page 544.	Pages 12 and 13 only admitted on transcript page 1364	BPVEFILTER-01-00191818	BPVEFILTER-01-00191840
4519 - R	Jones	Quality Assurance	6(b)	Monthly Management Report, dated 8/9/10	Admitted at page 2160, discussed page 14 at page 563, page 5 discussed at page 2175		BPVEFILTER-01-00191842	BPVEFILTER-01-00191864
4522 - R	Jones	Quality Assurance	6(b)	Monthly Management Report, dated 11/8/10	Admitted redacted on transcript page 1297, but not otherwise discussed.		BPVEFILTER-01-00194224	BPVEFILTER-01-00194246
4528 - R	Jones	Quality Assurance	6(b)	Monthly Management Report, dated 5/9/11	Admitted redacted on transcript page 1297, but not otherwise discussed.		BPVEFILTER-01-00195979	BPVEFILTER-01-00195998
4532 - R	Jones	Quality Assurance	6(b)	Monthly Management Report, dated 9/9/11	Admitted redacted on transcript page 1297, but not otherwise discussed.		BPVEFILTER-01-00196071	BPVEFILTER-01-00196090
4533 - R	Jones	Quality Assurance	6(b)	Monthly Management Report, dated 10/10/11	Admitted redacted on transcript page 1297, but not otherwise discussed.		BPVEFILTER-01-00196207	BPVEFILTER-01-00196230
4534 - R	Jones	Quality Assurance	6(b)	Monthly Management Report, dated 11/8/11	Admitted redacted on transcript page 1297, but not otherwise discussed.		BPVEFILTER-01-00105750	BPVEFILTER-01-00105775
4565	Jones	Quality Assurance	6(c)	FRE 1006 Chart - Plaintiff's Compilation Complaint Record Detail	Admitted at page 2160, pages 2-3 discussed at page 2343, page 283 discussed at page 564			
4603	Hyde	Design	5(e)	Kandarpa Deposition 07/19/2018 - Exhibit 13 - Recovery G2 Filter System - Femoral and Jugular/Subclavian Delivery Kits, Tradition 510(k), October 31, 2007		Admitted on transcript page 1477, but not displayed or discussed	BPV-17-01-00123629	BPV-17-01-124057
4607	Hyde	Quality Assurance	6(a)	Kandarpa Deposition 07/19/2018 - Exhibit 17 - Memorandum dated June 21, 2006 Subject: G2 Caudal Migration Failure Investigation Team Agenda, From Natatlie Wong		Admitted on transcript page 1477, page 1 displayed and document discussed generally	BPVE-01-01656342	BPVE-01-01656343
4820	Hyde	Quality Assurance	6(a)	Fermanich Deposition 3/17/17 - Exhibit 37: Health Hazard Evaluation memo from David Ciavarella to Gin Schulz., 2/15/06, Re: G2 Inferior Vena Cava Filter - Migration (3 pages)		Admitted on transcript page 284. First page displayed. Document only discussed generally.	BPVEFILTER-01-00008355	BPVEFILTER-01-00008357
4895	Hyde	Quality Assurance	6(d)	Meridian Filters Risk Analysis		Admitted on transcript page 1505. First and last pages displayed and discussed generally.		
4896	Hyde	Design	5(d)	Caudal Migration Testing of Meridian Optease		Admitted on transcript page 1511. First two pages displayed and discussed generally.		
4897	Hyde	Design	5(c)	G2 Express Product Performance Specification		Admitted on transcript page 1523. Page 37 displayed and discussed.		
5272	Jones, Hyde	Design	5(e)	Nov. 23, 2009 BPV's Eclipse Filter System Special 510(k) (K093659)	Admitted on transcript page 1422, page 2 discussed pages 1422 and 2027	Admitted on transcript page 1456. Pages 2 and 35 displayed and discussed.	BPV-17-01-00116991	BPV-17-01-00117153
5373	Jones, Hyde	Design	5(e)	Mar. 7, 2008 BPV's G2 Express Filter Special 510(k) (K080668)	Admitted on transcript page 1418, discussed generally and not displayed on pages 1418 and 2023	Admitted on transcript page 2454. Pages 1, 68, 70, 130 and 131 displayed and discussed.	BPV-17-01-00130498	BPV-17-01-00130730

5379	Jones	Design	5(e)	Aug. 12, 2008 BPV's G2X Filter Special 510(k) (K082305)	Admitted on transcript page 1419, discussed generally and not displayed on pages 1419 and 2023		BPV-17-01-00131320	BPV-17-01-00131596
5384	Hyde	Design	5(d)	G2 Express Feasibility Acute Animal study Report TR-07-05-18		Admitted on transcript page 5384. Pages 2 and 3 displayed and discussed.	BPV-17-01-00133028	BPV-17-01-00133050
5385	Jones, Hyde	Design	5(d)	G2 Express Filter Arm Fatigue Comparison TR-07-07-04	Admitted on transcript page 1643, only page 7 displayed	Admitted on transcript page 609. Pages 2, 5 and 13 displayed and discussed.	BPV-17-01-00133064	BPV-17-01-00133077
5486	Jones, Hyde	Design	5(e)	Dec. 17, 2009 Letter from BPV to FDA re Eclipse Filter System Response to FDA Questions (K093659)	Admitted on transcript page 1428, pages 7-9 displayed on pages 1428-30	Admitted on transcript page 2470. Pages 7, 8 and 9 displayed and discussed.	BPV-17-01-00145607	BPV-17-01-00145616
5488	Jones	Design	5(e)	June 21, 2010 Letter from BPV to FDA re Eclipse Filter System Response to FDA Questions (K101431)	Admitted on transcript page 1890, page 6 displayed at 2031		BPV-17-01-00145617	BPV-17-01-00145633
5563	Jones	Quality Assurance	6(f)	Standard Operating Procedures / Division Operating Procedures -- CQuality Assurance-STD-R002 Rev 14	Admitted on transcript pages 2318-19, page 12 displayed at 2319		BPV-17-01-00166838	BPV-17-01-00166868
5565	Jones, Hyde	Quality Assurance	6(f)	Standard Operating Procedures / Division Operating Procedures -- RA-STD-002 Rev 10	Admitted on transcript page 1709, page 18 displayed	Admitted on transcript page 1727. Page 1 displayed. Page 18 displayed and discussed.	BPV-17-01-00166947	BPV-17-01-00166968
5586	Jones, Hyde	Design	5(e)	May 20, 2010 BPV's Eclipse Filter Special 510(k) (K101431)	Admitted on transcript page 1432, pages 78-79 displayed at page 2029-30	Admitted on transcript page 2472. Pages 78, 79 and 80 displayed and discussed.	BPV-17-01-00171679	BPV-17-01-00171793
5587	Jones, Hyde	Design	5(e)	June 18, 2010 Letter FDA to BPV re FDA AI Demand re Eclipse (K101431)	Admitted on transcript page 1890, page 1 displayed at 2030	Admitted on transcript page 2615. Page 1 displayed and discussed.	BPV-17-01-00171794	BPV-17-01-00171796
5588	Jones, Hyde	Design	5(e)	Dec. 15, 2009 Letter FDA to BPV re FDA AI Demand re Eclipse (K093659)	Admitted on transcript page 1425, page 1 displayed	Admitted on transcript page 2469. Page 1 discussed.	BPV-17-01-00171797	BPV-17-01-00171799
5612	Jones	Design	5(e)	Nov. 17, 2009, FDA Contact Report re: cadual anchors (Filters and future submissions)	Admitted on transcript page 1890, not displayed		BPV-17-01-00171875	BPV-17-01-00171876
5929	Hyde	Design	5(d)	TR-07-12-01 (Test Report re G2 Express DV& V Flat Plate Fatigue and Corrosion)		Admitted at transcript page 616. Pages 1 and 17 displayed and discussed.	BPVE-01-00689537	BPVE-01-00689554
5934	Hyde	Design	5(d)	TP 07-02-12 (Flat Plate Fatigue Testing Protocol)		Admitted at transcript page 2742. Page 1 displayed and discussed.	BPVE-01-00769120	BPVE-01-00769127
5946	Hyde	Quality Assurance	6(e)	QMBR--July 2006		Admitted on transcript page page 2273. Page 22 displayed and discussed.	BPVE-01-01247634	BPVE-01-01247733
5967	Jones, Hyde	Quality Assurance	6(d)	G2 Risk Benefit Analysis (RBA-0003, Rev. 0)	Admitted on transcript page 1708, pages 1 and 3 displayed at 1709	Admitted on transcript page 2723. Page 2 displayed and discussed.	BPVE-01-01981272	BPVE-01-01981274
5970	Jones	Quality Assurance	6(a)	HHE re G2 Caudal Migration Febuary 15, 2006	Admitted on transcript page 1700, page 1 displayed		BPVEFILTER-01-00008355	BPVEFILTER-01-00008357
6013	Hyde	Design	5(e)	Dec. 27, 2010 Letter from BPV to FDA re Meridian		Admitted on transcript page 1285. Pages 1 and 4 displayed and discussed.	BPVEFILTER-01-01201729	BPVEFILTER-01-01201779
6089	Jones, Hyde	Design	5(c)	Product Development Cycle PPT	Admitted on transcript page 2089, page 3 displayed, page 13 displayed at page 2091	Admitted on transcript page 2084. Page 3 displayed and discussed.		
7961	Hyde	Quality Assurance	6(f)	Subset of CQuality Assurance-STD-24 is part of Def. Ex. 5691		Admitted on transcript page 1756. Page 1 displayed.		
7962	Hyde	Quality Assurance	6(f)	CQuality Assurance-STD-54 is part of Def. Ex. 5706		Admitted on transcript page 1767. Page 1 displayed.		
8358	Jones, Hyde	Design	5(d)	TR-09-10-15 -- Eclipse Flat Plate Fatigue and Corrosion Examination of the Vail (Eclipse) Filter	Admitted on transcript page 1890, page 6 displayed at page 2219	Admitted on transcript page 2759. Page 8 displayed and discussed.	BPV-17-01-00109017	BPV-17-01-00109024
8359	Jones, Hyde	Design	5(d)	TR-09-10-16 DV&V Eclipse Filter Arm Fatigue Comparison Study (Project #8113)	Admitted on transcript page 1638, page 1, 5, and 9 displayed at 1639-40	Admitted on transcript page 612. Pages 7 and 9 displayed and discussed.	BPV-17-01-00109027	BPV-17-01-00109036
8368	Jones	Design	5(d)	TP-09-10-15 Rev. 0 - Eclipse DV&V Flat Plate Fatigue and Corrosion Test Protocol	Admitted on transcript page 1890, page 1 and 7 discussed at page 2216-17		BPVEFILTER-42-00017728	BPVEFILTER-42-00017743
8373	Jones	Design	5(d)	TP-09-10-16 Rev. 0 - Eclipse Filter DV&V Arm Fatigue Evaluation Test Protocol	Admitted on transcript page 1890, generally discussed and not displayed		BPVEFILTER-20-00043369	BPVEFILTER-20-00043377
8546	Jones, Hyde	Design	5(d)	Draft Test Report re Rotary Beam Fatigue of Nitinol Wire	Admitted on transcript page 2210, generally discussed and page 3 discussed at page 2212	Admitted on transcript page 2757. Page 1 displayed and discussed.	BPV-17-01-00188406	BPV-17-01-00188410
8572	Hyde	Design	5(c)	G3 Meeting Minutes July 25, 2006		Admitted on transcript page 2359. Page 1 displayed and discussed.	BPV-17-01-00181762	BPV-17-01-00181763
8573	Hyde	Design	5(c)	G3 Meeting Minutes Nov 27, 2007		Admitted on transcript page 2360. Pages 1 and 4 displayed and discussed.	BPV-17-01-00181911	BPV-17-01-00181914
8574	Jones, Hyde	Design	5(d)	TR 09-10-10, Test Report Cyclic Fatigue Testing of Electropolished Vail Filter Wire	Admitted on transcript page 1635, page 3 and last page discussed at pages 1635-36	Admitted on transcript page 2755. Page 10 displayed and discussed.	BPVEFILTER-11-00027094	BPVEFILTER-11-00027103
8575	Jones, Hyde	Design	5(d)	TP 09-10-10, Test Protocol Cyclic Fatigue Testing of Electropolished Vail Filter Wire	Admitted on transcript page 1890, and 5 discussed at page 2199	Admitted on transcript page 2754. Page 5 displayed and discussed.	BPVE-01-00930038	BPVE-01-00930050
8583	Hyde	Design	5(c)	G3 Project Status Report April 19, 2006		Admitted on transcript page 2357. Page 1 displayed.	BPV-17-01-00183521	BPV-17-01-00183521